REMARKS

I. Status of the Claims

Claims 1 through 13 are pending in the application. Claim 1 is the sole independent claim. No new matter has been added. Reconsideration of the outstanding rejections is requested in view of the foregoing amendment and these remarks.

II. Summary of the Claimed Subject Matter

As amended, the claims are more closely directed to the identification and treatment of individuals having increased bone turnover. It has been discovered by the present inventors that selective estrogen receptor modulators (SERMs), and in particular ospemifene, have a more pronounced effect in individuals suffering from high bone turnover. Specifically, the ability of these compounds to prevent bone loss is highest when bone turnover is high. This discovery has important implications in identifying individuals who can most effectively be treated with SERMs to prevent bone loss, and provides direction in terms of how to treat those individuals to maximize the effect of the treatment.

III. Objection Under 37 C.F.R. § 1.175

Claim 3 is objected to as allegedly having the same scope as claim 2. Applicants respectfully traverse. Claim 2, in addition to ospemifene (formula (I)), claims isomers, salts, esters and metabolites of the compound, so that the claims do not have identical scope. Moreover, ospemifene is the (Z) isomer of formula (I).

IV. Rejection Under 35 U.S.C. § 112

Claim 5 has been rejected under 35 U.S.C. § 112, second paragraph, for an alleged lack of antecedent basis for "these markers." The foregoing amendment is believed

to overcome the rejection, deleting the phrase "these markers." Claim 5, as amended, identifies high bone turnover in an individual as a bone resorption marker and a bone formation marker higher than normal. Claims 12 and 13 have been added so that the broader and narrower range are not be in the same claim, requiring the levels for these markers to be 5% and 10% higher than normal, respectively. Claim 1 permits high bone turnover to be identified by measurement of a single marker, or both, as set forth in paragraph [0005] of the specification.

V. Rejections Under 35 U.S.C. § 112, First Paragraph

All of the claims have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not providing an enabling disclosure for the prevention of osteoporosis, as opposed to treatment.

The rejection is moot. As amended, the claims are directed to identifying and treating a population of individuals suffering from high bone turnover. Reconsideration and withdrawal of the amendment is respectfully requested.

However, applicants do not concede that the rejection has any merit. U.S. Patent Nos. 5,750,576 and 5,912,273 cover, *inter alia*, the use of ospemifene for the prevention or treatment of osteoporosis. The Food and Drug Administration (FDA) has approved at least one other SERM (Evista®) for prevention and treatment of postmenopausal osteoporosis, and the FDA has established guidelines to conduct clinical studies to prove the efficacy of the study drugs, *i.e.*, for both treatment and prevention. Thus, it is widely recognized that a product or use that reduces bone loss is potentially a preventative for osteoporosis, and the description in a patent application of a compound or use that has the potential to prevent bone loss is sufficient description under 35 U.S.C. § 112, first paragraph, to provide written description support a claim for treatment or prevention of osteoporosis. Note that the efficacy of a particular drug for prevention (as opposed to treatment), is a matter for the FDA to determine, in light of data developed in

clinical trials, and efficacy is not required to provide a written description under 35 U.S.C. § 112, first paragraph.

Claims 1 and 4 through 11 were rejected under 35 U.S.C. § 112, first paragraph, as "Applicant has not described with sufficient clarity a therapeutic active compound, which is a selective estrogen receptor modulator of triphenylalkene or triphenylalkane structure." (Office Action, pages 7-8). Applicants respectfully traverse. Suitable SERM compounds are disclosed with reference to the prior art at paragraph [0005] of the specification. The structural definition (triphenylalkene or triphenylalkane) is broad, but hardly a "laundry list," as suggested in the Office Action, especially when the compounds are also identified functionally, as being SERMs. In general, SERMs having triphenylalkene or triphenylalkane structure are known. The novelty in the present context lies in the use of these compounds in connection with identifying and treating individuals suffering from high bone turnover, as claimed. Reconsideration and withdrawal of the rejection is respectfully requested.

VI. Rejections Under 35 U.S.C. § 102

Claims 1-2 and 4 have been rejected under 35 U.S.C. 102(a) over *J. Medicinal Chem.*, Vol. 46, No. 7, pp 1081-111 (2003) (hereinafter "Jordan"); and claims 1-4 have been rejected under 35 U.S.C. 102(a) over U.S. 6,245,819 (hereinafter "Halonen"). Applicants respectfully traverse.

As amended, the claims require the step of identifying an individual having high bone turnover with a bone resorption marker and a bone formation marker. This subject matter was not rejected over the prior art, and it is believed to patentably distinguish both Jordan and Halonen.

The Examiner is correct that Jordan discloses ospemifene (Compound 30) and indicates that the compound is proposed to be used as a preventative for osteoporosis. However, Jordan does not disclose identifying individuals having high bone turnover. As

the reference does not expressly or inherently disclose all of the claim limitations, there is no anticipation.

Likewise, the Examiner is correct that Halonen discloses treating post-menopausal women with ospemifene (for vaginal dryness and sexual dysfunction). However, the reference does not teach identifying high bone turnover individuals, as presently claimed, so that there is no anticipation under 35 U.S.C. § 102.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

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